Supreme Court, U.S.
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NO.___

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1993

JEWISH MEMORIAL HOSPITAL, ET AL.,

Petitioners,

v.

COMMONWEALTH OF MASSACHUSETTS, ET AL.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT FOR THE COMMONWEALTH OF MASSACHUSETTS

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103 pp

QUESTION PRESENTED

Whether the Supreme Judicial Court for the Commonwealth of Massachusetts erred in declaring that the Massachusetts Department of Public Welfare's Medicaid regulations governing preadmission screening and level of care do not violate federal utilization review requirements prescribed by Title XIX of the Social Security Act.

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PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME JUDICIAL COURT
FOR THE COMMONWEALTH OF MASSACHUSETTS

The Jewish Memorial Hospital and Rehabilitation Center, Youville Rehabilitation and Chronic Disease Hospital, New England Sinai Hospital, St. John of God Hospital, Lawrence J. Kerzner, M.D., Henry H. Cho, M.D.,

Lawrence S. Hotes, M.D., and John A. Bolzan, M.D. petition for a writ of certiorari to review the judgment of the Supreme Judicial Court of the Commonwealth of Massachusetts.[1] Respondents are the Commonwealth of Massachusetts, the Massachusetts Division

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[1] Other parties who were appellants in the proceeding in the Supreme Judicial Court are the Massachusetts Respiratory Hospital, Middlesex County Hospital, Shaughnessy-Kaplan Rehabilitation Hospital, Worcester County Hospital, Mehbooba Anwar, M.D., David J. Takvoryan, M.D. and Ronald J. Pantano, M.D.

of Medical Assistance,[2] Bruce M. Bullen, as he is the Commissioner of the Division of Medical Assistance[3] and the Massachusetts Department of Public Health.

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[2] Pursuant to House Bill No. 5090, the Division of Medical Assistance was created to assume responsibility for the Medical Assistance (Medicaid) program for which the Department of Public Welfare had previously been responsible. House Bill No. 5090 was a reorganization bill submitted by the Governor to the General Court. Pursuant to Article LXXXVII of the Amendments to the Massachusetts Constitution, the Bill became effective July 17, 1993.

[3] At the time the lawsuit was filed in Superior Court, Carmen Canino Siegrist was the Commissioner of the Department of Public Welfare and Bruce M. Bullen was the Associate Commissioner.

OPINION BELOW

The opinion of the Supreme Judicial Court for the Commonwealth of Massachusetts (Appendix, infra, A-1 - A-29) is reported at 416 Mass. 132 (1993) and 617 N.E.2d 598 (1993).

JURISDICTION

The judgment of the Supreme Judicial Court for the Commonwealth of Massachusetts was entered on August 11, 1993. A petition for rehearing was denied on September 23, 1993. (Appendix, infra, A-30 - A-31). The jurisdiction of this Court is invoked under 28 U.S.C. §1257.

STATUTES AND REGULATIONS

The Commonwealth of Massachusetts' Medicaid regulations challenged in this case, 106 Code Massachusetts Regulations (CMR) Sections 435.401 and 435.409 to 435.410 effective March 1, 1991, the relevant provisions of the federal Medicare and Medicaid Acts, specifically, 42 U.S.C. §§1395x(k), 1396a(a)(30)(A), 1396b(g)(6)(A), 1396b(i)(4), 1396n(b), 1320c-1, 1320c-3(a)(1), 1320c-7, and the federal Medicare and Medicaid regulations, specifically, 42 C.F.R. §§482.30, 462.104(d), are reproduced in the Appendix (infra, pp. A-32 - A-61).

STATEMENT OF THE CASE

This case involves a challenge under the federal Medicaid statute, 42 U.S.C. §1396b(i)(4) and 42 U.S.C. §1396n(b), to regulations adopted by the Commonwealth of Massachusetts Department of Public Welfare prescribing "level of care" criteria to be applied to determine the medical necessity and appropriateness of placement of Medicaid patients in chronic disease and rehabilitation hospitals. The text of the regulations at issue is contained at Appendix, A-32 - A-47.

The Supreme Judicial Court incorrectly held that the Department of Public Welfare's preadmission screening regulation and level of care criteria did not violate federal utilization review requirements. The Supreme Judicial Court's decision permits the Commonwealth

of Massachusetts to bar Medicaid patients from admission to chronic disease and rehabilitation hospitals in instances where physician members of the hospitals' utilization review committees determine the admission to be medically necessary. Under the level of care regulations and preadmission screening program, the Department of Public Welfare applies standards and procedures, that are inconsistent with those applicable to the Medicare program, to determine whether the admission is reimbursable under the Medicaid program. The Department has not sought or received permission from the Secretary of Health and Human Services to employ utilization review standards or procedures which deviate from Medicare utilization review requirements.

Procedural Background

On November 26, 1990, petitioners commenced this action against the respondents in the Superior Court Department of the Trial Court for the Commonwealth of Massachusetts. The petitioners sought declaratory and injunctive relief. Among other things, the complaint alleged that the Department's regulations governing the Medicaid program for chronic disease and rehabilitation hospitals including the preadmission screening program violated federal utilization review requirements, including 42 U.S.C. §1396b(i)(4) and the waiver provision in 42 U.S.C. §1396n(b). The petitioners moved for partial summary judgment and the respondents moved for summary judgment on all claims. On June

18, 1991, the Superior Court issued summary judgment in favor of the respondents on all claims. On May 1, 1992, the Superior Court issued a declaratory judgment which stated, among other things, that the Department's regulations did not violate the requirements of 42 U.S.C. §1396b(i)(4).

The petitioners appealed from the Superior Court's judgment to the Appeals Court of the Commonwealth of Massachusetts. The Supreme Judicial Court for the Commonwealth of Massachusetts, on its own initiative, accepted the case for direct appellate review. On August 11, 1993, the Supreme Judicial Court ruled, in relevant part, that the preadmission screening regulation does not concern federal utilization review requirements by its

terms and that the level of care regulations fall within the Department's authority to perform utilization control under 42 U.S.C. §1396a(a)(30)(A). Jewish Memorial Hospital, 416 Mass. 136-137, 139, 617 N.E.2d 602-603. The petitioners filed a Petition for Rehearing which was denied on September 23, 1993.

The Medicaid Program

In 1965, Congress established the Medicaid Program as Title XIX of the Social Security Act, 42 U.S.C. §§1396, et seq., to provide federal financial assistance to states that choose to reimburse the cost of medical care for certain indigent persons. States participating in the Medicaid program must operate under a state plan that has been approved by the Secretary of Health

and Human Services ("the Secretary") as conforming with federal requirements. 42 U.S.C. §§1396a(a), 1396a(b).

Under federal law, Medicaid reimbursement is mandated for a hospital placement which is medically necessary. See 42 U.S.C. §1396 (Federal Medicaid program enables states to provide medical assistance "to meet costs of necessary medical services"). See also 42 U.S.C. §§1396a(a)(10)(A), 1396d(a)(1) (State must provide coverage for inpatient hospital services). The Massachusetts State Plan provides for coverage of inpatient hospital services.

"Utilization review" is the process which determines whether patient care services are medically necessary. It involves considerations of whether patient care is appropriately provided at

different "levels of care," such as, in a hospital, nursing home or other setting. See 42 U.S.C. §1395x(k), 42 C.F.R. §482.30 [Medicare] and 42 U.S.C. §1396b(i)(4) [Medicaid]. To determine whether inpatient hospital services are medically necessary and therefore reimbursable under the Medicaid program, federal law requires that a physician certify that the admission is medically necessary at the time the Medicaid patient is admitted. 42 U.S.C. §1396b(g)(6)(a).

Federal law requires that the same utilization review standards and

procedures govern the Medicare[4] and Medicaid programs. Specifically, 42 U.S.C. §1396b(i)(4) provides that utilization review for Medicaid patients be performed "with the same standards and procedures and the same review committee or group" as exist under the Medicare program. Under the Medicare program, hospital utilization review committees are composed of two or more physicians (with or without participation of other professional personnel) who are responsible for determining the medical necessity of services furnished by the hospital. 42 U.S.C. §1395x(k), 42 C.F.R.

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[4] The Medicare program is a program of health care insurance administered by the federal government for individuals sixty-five years of age and older and certain disabled persons. 42 U.S.C. §1395, et seq.

§482.30. Their determinations are subject to review only by a federally approved peer review organization (PRO). 42 U.S.C. §1320c(1) and (7) and 42 U.S.C. 1396b(i)(4). PROs are comprised of licensed doctors of medicine who are authorized to review services provided to Medicare recipients to determine whether they are medically necessary, consistent with professionally recognized standards of care, and furnished in an appropriate setting. 42 U.S.C. §§1320c-1, 1320c-3(a)(1).

Under §1396b(i)(4), the state may not deviate from the utilization review standards and procedures prescribed by the Medicare program "unless the state has demonstrated to the Secretary of Health and Human Services that it has developed a superior method and the

Secretary has waived the requirements of §1396b(i)(4)." The record in this case is clear that the Department did not apply for a waiver or demonstrate to the Secretary that it has developed a superior system. A federal regulation provides that a state Medicaid agency, such as the Massachusetts Department of Public Welfare is "considered incapable of performing utilization and quality review functions in an effective manner, unless the state demonstrates to the satisfaction of HCFA [the Health Care Financing Administration] that it will act with complete independence and objectivity." 42 C.F.R. §462.104(d). The state made no demonstration to HCFA under this regulation.

The Level of Care and Preadmission Screening Regulations

The level of care and preadmission screening regulations conflict with the utilization review standards and procedures applied under the Medicare program. An uncontroverted physician affidavit contained an exhibit which showed the inconsistencies between the utilization review standards and procedures under the Department's regulations and the utilization review standards and procedures applied under the Medicare program. Specific examples of how the regulations violate federal utilization review requirements are set forth below.

Under the level of care regulations at issue, "the Department or its agent", applies the level of care criteria in §§435.409 and 435.410 "to determine the medical necessity and appropriateness of placement" in a chronic disease and rehabilitation hospital. Under the preadmission screening program at section 435.401(B) the Department or a hospital with delegated status is required to apply the level of care criteria to establish whether there is a need for hospitalization prior to admission. Under sections 435.401(B) and 435.409(A)(1) of the regulations, the Department will pay for services only if it or its designated agent has approved a patient admission by applying the level of care regulations. In contrast, under federal law, such determinations are made

by physician members of a hospital's utilization review committee. 42 U.S.C. §1395x(k), 42 C.F.R. §482.30.

The level of care criteria provide a mechanical checklist method for determining the medical necessity and appropriateness of placement. Under section 435.409(A)(1)(c), a patient must require "daily or more frequent physician supervision" or "the constant availability of medical services and equipment ordinarily available only in a hospital setting." The record contains uncontroverted affidavits submitted by physicians who attested that many patients who would not meet these standards would be placed at serious risk by being denied admission to the hospital.

Section 435.409 provides that "the [Department's] evaluator shall use as a guide the Adult Appropriateness Evaluation Protocol [AEP]" in applying the "general criteria" listed under section 435.409(A)(1). Under the federal Medicare program the AEP is not referenced in any rule or regulation. There were uncontroverted affidavits submitted by physicians which stated that under the Medicare program, the AEP is used as a guide by nurse reviewers to approve but never to deny a patient admission to a hospital. Also, the AEP is not used by physicians who rely upon their knowledge of generally accepted medical practice and the actual availability in non-hospital settings of medical resources required by the patient.

The affidavits submitted by physicians stated that if the criteria in the Department's regulations were followed by hospital utilization review committees, their decisions regarding the appropriateness of Medicaid patients' admissions would be different than the decisions mades under the Medicare utilization review process.

Under section 435.409(A)(2) the Department has the authority to override the level of care criteria contained in section 435.409(A)(1) if its own clinical staff makes a determination that chronic disease and rehabilitation hospital care is more cost effective and that the patient's complex medical condition prevents an alternative placement. Under federal law only a PRO is authorized to review determinations made by a

hospital's utilization review committee. 42 U.S.C. §1395x(k). In effect, the Department is functioning as a PRO without the authority to do so. 42 C.F.R. §462.104(d).

REASONS FOR GRANTING THE WRIT

I. CONGRESS HAS MANDATED UNIFORM UTILIZATION REVIEW STANDARDS AND PROCEDURES FOR THE MEDICAID AND MEDICARE PROGRAMS

The decision of the Supreme Judicial Court of Massachusetts conflicts with the federal statutory requirement that utilization review for Medicaid patients be performed "with the same standards and procedures and the same review committee or group as exist under the Medicare program." 42 U.S.C. §1396b(i)(4). Congress has established in 42 U.S.C. §1396b(i)(4) principles for nationally uniform utilization review standards and procedures for the Medicaid program. These principles are important because they ensure that a determination as to

whether a Medicaid recipient requires an inpatient hospital placement will be made by physicians based on medical necessity and professionally recognized standards of care. The writ of certiorari should be granted because the Massachusetts regulations at issue in this case establish utilization review standards and procedures which conflict with federal standards and procedures and interfere with hospitals' and physicians' ability to admit and provide treatment to Medicaid patients.

Congress has a legitimate concern that the two principal health care benefit programs which it funds (Medicare and Medicaid) use the same standards to determine whether services are considered medically necessary and therefore reimbursable. Nationwide, millions of

individuals are covered by state Medicaid programs. If each state is allowed to develop its own standards of utilization review, then Congress' mandate of uniform standards will be undermined.

The lack of uniform standards will result in different coverage decisions based solely on whether the patient's hospitalization is being paid by the Medicare or Medicaid program. Conflicting state and federal utilization review requirements will be particularly harmful in the area of patients dually eligible for Medicare and Medicaid. A dually eligible patient may find himself/herself in the untenable situation where Medicare concludes that inpatient hospitalization is medically necessary but Medicaid reaches the opposite conclusion. The result may be

the denial by the state Medicaid program of payment for Medicare coinsurance and deductible amounts, amounts which Congress has mandated that state Medicaid programs cover if medically necessary. 42 U.S.C. §1396a(a)(10)(E). Congress sought to prevent such a scenario by directing that the same utilization standards be used for both programs.

II. THE SUPREME JUDICIAL COURT'S RULING THAT PREADMISSION SCREENING DOES NOT CONCERN UTILIZATION REVIEW IS CONTRARY TO FEDERAL REGULATIONS GOVERNING THE MEDICAID PROGRAM.

The Supreme Judicial Court erred in ruling that "[p]readmission screening" ... does not concern utilization review by its terms." Jewish Memorial Hospital, 416 Mass. 139, 598 N.E.2d 603. Under the Medicare and Medicaid programs, utilization review encompasses

preadmission review. The federal regulation 42 C.F.R. §482.30 entitled "Condition of participation: Utilization review" governs review of services provided to patients entitled to benefits under the Medicare and Medicaid programs. Section 482.30(c)(1)(i) requires the hospital utilization review plan to provide for review of the medical necessity of "admissions" to the hospital. Section 482.30(c)(2) provides that "[r]eview of admissions may be performed before, at, or after hospital admission." Preadmission screening is a review of the medical necessity of an admission before a patient is admitted to the hospital. Under the federal regulation, 42 C.F.R. §482.30 utilization review includes preadmission review.

III. THE SUPREME JUDICIAL COURT'S DISTINCTION BETWEEN LEVEL OF CARE REGULATIONS GOVERNING PLACEMENT FOR REIMBURSEMENT PURPOSES AND PLACEMENT FOR MEDICAL NECESSITY PURPOSES CONFLICTS WITH THIS COURT'S OPINION IN BLUM V. YARETSKY.

The Supreme Judicial Court incorrectly ruled that the level of care criteria, 106 CMR §§435.409 and 435.410, "concern the question whether a placement in a chronic disease hospital is appropriate for reimbursement purposes" rather than whether placement in such a hospital is medically necessary, citing the federal utilization control statute, 42 U.S.C. §1396a(a)(30)(A) as authority for its ruling. Jewish Memorial Hospital, 416 Mass. 136-137, 598 N.E.2d at 602-603. This distinction between level of care regulations governing placement for reimbursement purposes and

placement for medical necessity purposes is nonexistent under federal law. Under federal law, reimbursement is not simply appropriate but is mandated for an inpatient hospital placement which is medically necessary where coverage for inpatient hospital services is included in the state plan.

As this Court noted, under the Medicaid program, a patient must meet two conditions to obtain financial assistance. S/he must meet eligibility criteria defined in terms of income and resources and s/he must seek medically necessary services. Blum v. Yaretsky, 457 U.S. 991, 1006 (1982), 42 U.S.C. §1396. Federal law is clear that the physician, not the state agency in charge of the Medicaid program, is to certify that hospital services are medically

necessary at the time the Medicaid patient is admitted. 42 U.S.C. §1396b(g)(6)(A). Contrary to federal law, under the Department's regulations the state either makes the determination or controls the determination by establishing the standards to be applied.

Medical necessity determinations are identical to level of care determinations. Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1332 (5th Cir. 1992), cert. denied, _U.S._, 113 S. Ct. 812 (1992) (utilization review organization makes medical decisions in deciding what benefits are available).

The authority to perform utilization control is not the same as the authority to perform utilization review, i.e., to make medical necessity determinations. The latter has been delegated by Congress

in 42 U.S.C. §1395x(k)(2) to physician members of hospital utilization review committees, subject to review only by the PRO. To comply with utilization control requirements, the state is required to show that a hospital physician has certified the need for inpatient services at the time of admission and recertified that need at least every sixty days during the patient's stay in accordance with 42 U.S.C. §1396b(g)(6)(A). States which fail to make a satisfactory showing are subject to a decrease in federal financial participation ("FFP"). See State of Hawaii v. Heckler, 760 F.2d 1031 (9th Cir. 1985). Utilization control does not allow states to intrude upon utilization review. Due to their inherent conflict of interest as a payor, states are considered incapable of

performing utilization review. 42 C.F.R. §462.104(d).

The record contained uncontroverted physician affidavits which stated that many patients who would not meet the level of care criteria would be placed at serious risk by being denied admission to the hospital. By following the regulations hospital physicians would be in the position of denying admission to patients in need of services generally available only in a hospital and acting contrary to the best interests of patients. The level of care criteria at 106 CMR §§435.409 and 435.410, although adopted as a cost limitation program, could corrupt a physician's medical judgment. See Wilson v. Blue Cross of Southern California, 222 Cal. App. 3d 660, 666 (1990), citing Wickline v. State

of California, 192 Cal. App. 3d 1630, 1647 (1986), cert. granted, 231 Cal. Rptr. 560, 727 P.2d 753, review dismissed, cause remanded, 239 Cal. Rptr. 805, 741 P.2d 613 (1987) (insurance cost limitation program which subjects the treating physician's determination of medical necessity to external utilization review permits corrupt medical judgment). Cf. Hughes v. Blue Cross of Northern California, 215 Cal. App. 3d 832, 847 (1989), cert. dismissed, 495 U.S. 944 (1990) (utilization review process which relies on restrictive standard of medical necessity at variance with community standards operates in conscious disregard of insured's rights). Even the Supreme Judicial Court acknowledged: "It is no doubt true that the availability of reimbursement and the level of any

available reimbursement might indirectly affect medical judgments as to what care to provide to a patient." Jewish Memorial Hospital, 416 Mass. at 136, 617 N.E.2d at 602.

IV. THE SUPREME JUDICIAL COURT'S FAILURE TO RULE THAT MASSACHUSETTS WAS REQUIRED TO OBTAIN A WAIVER IS CONTRARY TO FEDERAL STATUTORY PROVISIONS.

The Supreme Judicial Court erred in not ruling that the Commonwealth of Massachusetts was required to obtain a waiver of federal utilization review requirements in the manner provided for by 42 U.S.C. §1396n(b). Under 42 U.S.C. §1396b(i)(4), the state may not deviate from the utilization review procedures prescribed by the Medicare program "unless the State has demonstrated to the Secretary of Health and Human Services

that it has developed a superior method and the Secretary has waived the requirements of Section 1396b(i)(4)."[5] There is nothing in the record to indicate that the Department applied for a waiver or demonstrated to HCFA that it has developed a superior method.

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[5] Examples of how the level of care regulations and preadmission screening program apply different standards and procedures and a different review committee or group than exist under the Medicare program are set forth at pp. 16-21, supra.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: December 20, 1993

APPENDIX

JEWISH MEMORIAL HOSPITAL & others[1]
vs. COMMONWEALTH
& OTHERS.[2]

Suffolk. May 6, 1993. -
August 11, 1993

PRESENT: LIACOS, C.J. WILKINS,
ABRAMS, NOLAN, & LYNCH, J.J.

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[1] Youville Rehabilitation and Chronic Disease Hospital, St. John of God Hospital, Massachusetts Respiratory Hospital, Middlesex County Hospital, New England Sinai Hospital and Rehabilitation Center, Shaughnessy-Kaplan Rehabilitation Hospital, Worcester County Hospital, and the following physicians, each of whom is associated with one of the plaintiff hospitals: Lawrence J. Kerzner, Henry H. Cho, John A. Bolzan, Mehbooba Anwar, David J. Takvoryan, Lawrence S. Hotes, and Ronald J. Pantano.

[2] The Department of Public Welfare, the Commissioner of that department, the associate commissioner of that department who is responsible for the administration of the Commonwealth's Medicaid program, and the Department of Public Health.

CIVIL ACTION commenced in the Superior Court Department on November 26, 1990.

The case was heard by Patrick J. King, J., on motions for summary judgment.

The Supreme Judicial Court on its own initiative transferred the case from the Appeals Court.

Edward D. Kalman (Rochelle H. Zapol with him) for the plaintiffs.

Judith Fabricant, Assistant Attorney General (William L. Pardee, Assistant Attorney General, with her) for the Commonwealth & others.

WILKINS, J. The plaintiff hospitals appeal from a declaratory judgment entered on May 1, 1992, in the Superior Court, following the filing of cross-motions for partial

summary judgment. That judgment upheld the lawfulness of certain regulations of the Department of Public Welfare (department) and the lawfulness of the department's 1990 request for proposals for the development of specialized facilities. We transferred the case from the Appeals Court on our own motion.

The judgment upheld 106 Code Mass. Regs. §§ 435.401 to 435.411 (1991), inclusive, against a claim that they violated the requirements of G.L. c. 6A, §32 (1992 ed.), the requirements of G.L. c. 118E, § 4 (1992 ed.), and Federal standards for Medicaid reimbursement. Those regulations are a portion of the department's regulations governing

participation in the Massachusetts Medicaid program by chronic disease, rehabilitation, and Department of Public Health hospitals and units within other facilities that perform chronic disease or rehabilitation services.[3] The plaintiffs rightly complain that the judgment fails to address their contentions that other, later numbered, sections of the department's regulations on the

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[3] The declaratory judgment only referred to 106 Code Mass. Regs. §§ 435.401-435.410 (1991). However, because of renumbering of the regulations made after argument of the case in the Superior Court but before the judgment was entered, it is clear that the judgment should have included 106 Code Mass. Regs. § 435.411 (1991) with the other regulations.

same general subject are unlawful. The complaint cited such regulations and alleged violations of law that necessarily concerned those regulations. We shall remand the case for consideration of the plaintiffs' challenges not disposed of by the declaratory judgment.

The judge rejected the plaintiffs' challenges to the department's plan to seek the development of specialized facilities to provide care for persons who have conditions that do not require hospitalization but do require services not generally available in a nursing home. In the summer of 1990, the department issued a request for proposals (RFP) for the development of such

specialized facilities. In November, 1990, the department awarded contracts to twenty bidders, three of whom are plaintiff hospitals in this case. The plaintiffs challenge the department's procedure for the creation and operation of such facilities, arguing, among other things, that the RFP violates Federal requirements for Medicaid programs and that the RFP, and the regulations together, violate rights protected by the Fourteenth Amendment to the United States Constitution.

The declaratory judgment did not dispose of the entire case, and, strictly speaking, absent a direction from the judge, the

judgment was not an appealable final judgment. See Mass. R. Civ. P. 54 (b), 365 Mass. 820 (1974). We shall, however, deal with the plaintiffs' objections to the judgment that was entered.[4]

1. The regulations. We consider first the plaintiffs'

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[4] It was within the judge's discretion to deny the plaintiffs' motion to add the Rate Setting Commission as a party and claims seeking a declaratory judgment on issues not raised in the complaint in this case.

There is also before us an appeal from the motion judge's denial in March, 1993, of the plaintiffs' motion under Mass. R. Civ. P. 60(b)(6), 365 Mass. 828 (1974), to vacate judgment based on events that occurred after the entry of the declaratory judgment. The judge did not abuse his discretion in denying that motion.

challenges to the lawfulness of certain aspects of 106 Code Mass. Regs. § 435.401 - 435.410. We address in order the plaintiffs' arguments that certain regulations violate (a) G. L. c. 6A, § 32, (b) G.L. c. 118E, § 4, and (c) Federal Medicaid reimbursement standards.

(a) The plaintiffs advance four arguments challenging regulations as violative of G.L. c. 6A, § 32. First, the plaintiffs claim that the department improperly reserved to itself in § 435.409 (A) the right to review the medical necessity of the placement of a patient in a chronic disease hospital. Section 435.409 (A) provides that "[t]he following level-of-care criteria will be used

by the Department or its agent to determine the medical necessity and appropriateness of placement in chronic disease...hospitals." It is claimed that this preadmission screening provision is contrary to a provision in § 32, added by St. 1988, c. 270, § 1, concerning rates of reimbursement for administratively necessary days. The provision in § 32 states that "[d]eterminations as to the medical necessity of patient care shall only be made by physician members of each hospital's utilization review committee, and may only be subject to review by [authorized peer review organizations]." An administratively necessary day is a day in which a Medicaid recipient

who is a hospital inpatient could properly be treated in a facility providing a lower level of care but no such facility is reasonably available. See New England Memorial Hosp. v. Rate Setting Comm'n, 394 Mass. 296, 298 (1985). The plaintiffs make no reasoned argument in support of their claim that a regulation concerning only preadmission screening (§ 435.409) is unlawful because of statutory language concerning determinations as to the medical necessity of

inpatient care. We reject this challenge to § 435.409 (A).[5]

Second, plaintiffs challenge 106 Code Mass. Regs. §§ 435.409 and 435.410, both of which concern the level of care that a patient must require to be considered an appropriate chronic disease hospital placement. The claim is that other language added to G. L. c. 6A, § 32, by St. 1988, c. 270, § 1, forbids the department from becoming involved in medical determinations in the way that it is claimed that §§ 435.409 and 435.410 allow. That language states that

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[5] Any challenge to 106 Code Mass. Regs. § 435.412 (1991) is outside the scope of the declaratory judgment.

"[d]eterminations of the medical necessity of care provided to patients by non-acute hospitals shall not be subject to any substantive standards other than generally accepted medical practice." We see no conflict. The challenged regulations concern the question whether a placement in a chronic disease hospital is appropriate for reimbursement purposes. The statutory language concerns the determination of the medical necessity for care in such a hospital. The regulation and statute relate to different subjects. It is no doubt true that the availability of reimbursement and the level of any available reimbursement might indirectly

affect medical judgments as to what care to provide to a patient. We do not, however, read the statutory language as barring the department from having control over the appropriateness for reimbursement purposes of hospital admissions for which public funds are expended. See 42 U.S.C. § 1396a (a)(30)(A) (Supp. III 1991) (department has an obligation, among other things, to "provide such methods and procedures relating to the utilization of, and the payment for, care and services...as may be necessary to safeguard against unnecessary utilization of such care and services").

A somewhat similar argument was rejected in Norfolk County Hosp. v.

Commonwealth, 25 Mass. App. Ct. 586, 592(1988), in which the court held that prior, similar regulations, defining an appropriate placement in a chronic disease hospital, did not violate the prohibition in G.L. c. 118E, § 4, against the department formulating "medical standards and criteria." Chapter 270 of the Acts of 1988 was enacted approximately six months after the Appeals Court opinion in the Norfolk County Hosp. case. If the Legislature had intended to bar the department from promulgating criteria concerning the appropriateness for reimbursement purposes of a placement in a chronic disease hospital, it should have been, and, we think, would have been, more specific.

Third, the plaintiffs argue that the department's regulations do not comply with the mandate of G.L. c. 6A, §32, that the administratively necessary day rate "shall only apply to patients for whom medically necessary care is usually provided to public assistance recipients admitted to nonhospital facilities within a twenty-five mile radius of the domicile of any individual recipient or his family." The regulations which specify when administratively necessary days are reimbursable are 106 Code Mass. Regs. §§ 435.413 and 435.414 (1991), and are beyond the scope of the declaratory judgment. The department was not obliged to deal with this subject in its

definition of administratively necessary days in § 435.402 (A).

Fourth and finally, the plaintiffs argue that the department has failed to conform its regulations to the rights of appeal established in G.L. c. 6A, § 32, as amended by St. 1988, c. 270, § 1, concerning a determination that administratively necessary day rates shall apply to a patient. The plaintiffs point to § 435.409 (B) as failing to meet the statutory standard. That section, however, provides an appeal mechanism concerning preadmission screening decisions and does not involve determinations as to administratively necessary day rates. That regulation is the only

one within the scope of the declaratory judgment that the plaintiffs challenge on the ground that it fails to provide proper appellate procedures.[6]

(b) The plaintiffs also argue that aspects of the regulations violate G.L. c. 118E, § 4, because

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[6] The plaintiffs' challenge to 106 Code Mass. Regs. § 435.417 (1991) is outside the range of the judgment, but it would fail for the same general reason, that is, the subject matter of the decision involved in § 435.417 is not one as to which G.L. c. 6A, § 32 (1992 ed.), mandates a particular appellate process.

What we say in Youville Hosp. v. Commonwealth, post (1993), concerning the hospitals' rights to declaratory relief concerning administratively necessary day rates and St. 1988, c. 270, § 1, would also justify not granting the plaintiffs relief on this fourth point.

they contain "medical standards and criteria" which § 4 states the department may not formulate.[7] This is an up-to-date reiteration of the claims made unsuccessfully by the plaintiffs in Norfolk County Hosp. v. Commonwealth, supra at 591-592, and noted earlier in this opinion. The prohibition in § 4 against the department's formulating medical standards and criteria bars the department from regulating the

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[7] Section 4 of G.L. c. 118E (1992 ed.) provides that "[i]n administering the program the department shall formulate such methods, policies, procedures, standards and criteria, except medical standards and criteria, as may be necessary for the proper and efficient operation of the plan in a manner consistent with simplicity of administration and the best interests of the recipients."

nature and degree of medical services that shall be provided to a patient. It does not, however, bar the department from determining for reimbursement purposes the medical necessity and appropriateness of a placement in a chronic disease hospital using criteria such as the adult appropriateness evaluation protocol referred to in § 435.409.

(c) The plaintiffs are wrong in asserting that 106 Code Mass. Regs. § 435.409 (A) violates Federal utilization review requirements. They have misunderstood the operation of the challenged regulation. An independent physician, not the department, has the final say on the preadmission placement decision. 106 Code Mass.

Regs. § 435.401 (B). Although a hospital must have a utilization review plan that meets Federal requirements (42 U.S.C. § 1395x[k] [1988]) in order to qualify for Medicaid reimbursement (42 U.S.C. § 1396b[i] [4] [1988]), § 435.409 (A) in no way impedes the plaintiffs from doing so. Moreover, there is no Federal prohibition against the establishment of State procedures that supplement Federal utilization review requirements. Preadmission screening, which is the subject of § 435.409(A), is a process separate from that addressed by the Federal requirements and does

not concern utilization review by its terms.[8]

2. Requests for proposals. The plaintiffs advance various objections to the department's request for proposals (RFP) for the furnishing of care to Medicaid recipients who do not need to be hospitalized in an acute care hospital, but need services not generally available in a nursing home. No contract had been negotiated at the time that summary judgment was ordered. The plaintiffs have not shown that the department's RFP is unlawful.

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[8] Challenges to § 435.412 in connection with utilization review are not before us.

The department had statutory authority to make agreements of the type contemplated with chronic disease and rehabilitative hospitals such as the plaintiffs. See G.L. c. 118E, § 4, and G.L. c. 118E, § 2(g) (1992 ed.), defining "provider." The prohibition of St. 1992, c. 133, § 2, line-item 4402-4200, against the department's selectively contracting for chronic hospital services before July 1, 1993, is not shown to be violated, was enacted after the judgment was entered in this case, and implicitly recognizes the department's authority generally to enter into such contracts.

The RFP provides that hospital reimbursement will be at negotiated rates. The Commonwealth's Medicaid

plan, then in effect, did not permit reimbursement at negotiated rates. Federal law requires that rates of reimbursement be in accordance with a Federally approved State plan. 42 C.F.R. § 447.253(i)(1992). See Quincy City Hosp. v. Rate Setting Comm'n, 406 Mass. 431, 433 (1990) (State choosing to participate in Medicaid "must submit to [Federal agency] a 'State plan' for medical assistance that comports with Federal statutory and regulatory requirements"). The defendants grant that the State plan would have to be amended in order to implement the RFP program. The judgment entered on remand should acknowledge this circumstance (adjusted, if necessary, to current

circumstances). The obligation to amend the State plan need not be satisfied before any contracts at negotiated rates are executed. See 42 C.F.R. §§ 430.20(b) and 447.256(c)(1992).

The plaintiffs' argument is premature that public notice is required before the department may contract at negotiated rates pursuant to the RFP. See 42 C.F.R. § 447.205 (1992). Moreover, it is doubtful that the plaintiffs, who already know of the circumstances, have any basis for complaint. See California Ass'n of Bioanalysts v. Rank, 577 F. Supp. 1342, 1349-1350 (C.D. Cal. 1983). The underlying issue as to whether public notice is required is whether reimbursement at

a negotiated rate is a "significant proposed change" in the department's "methods and standards for setting payment rates for services." 42 C.F.R. 447.205(a). The addition of a new method of payment seems to be a change in the method of setting payment rates for services. Whether the change is significant may depend on facts not before us, such as the impact on Medicaid expenditures. The fact that the RFP would affect only about 260 Medicaid recipients suggests that the change may not be significant in its general impact. See Missouri Dep't of Social Servs.

v. Sullivan, 957 F.2d 542, 545 (8th Cir. 1992).[9]

The plaintiffs probably have no standing to challenge the RFP program on the ground that it violates Federal law governing Medicaid patients' freedom of

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[9] The plaintiffs' complaint that there are no findings that the negotiated rates are reasonable and adequate and in accordance with law (42 U.S.C. § 1396a [a][13][A][Supp. III 1991]) is also premature. Because there were no negotiated rates, there could be no such findings.

The plaintiffs' argument that the RFP will violate Federal utilization review requirements is wrong. Nothing in the RFP exempts contract facilities from utilization review requirements that are otherwise applicable.

choice.[10] In any event, the RFP opens up a new option for such patients and in no way restricts their choices of facilities. The record does not support the claim that the RFP violates the requirement of 42 U.S.C. § 1396a(a)(10)(1988 & Supp. III 1991), and implementing regulations (42 C.F.R. §§ 440.230 and

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[10] The plaintiffs state briefly that the RFP program in certain of its aspects denies them and their patients equal protection of the laws and violates due process guarantees. The plaintiffs make no showing that classifications made by the program are constitutionally inappropriate or that they have standing to raise their patients' constitutionally-based arguments. The plaintiffs' claim that there was a dispute of material fact on the constitutional issues that barred the granting of summary judgment lacks merit.

440.240[1992]), concerning equality in the amount, duration, and scope of each service provided the categorically needy group and the covered medically needy group.

3. Although we affirm the provisions of the judgment entered, the case is remanded for consideration of such issues in the complaint that were not decided by the declaratory judgment. Circumstances may have changed so that certain issues are no longer important or are perhaps even moot. In the judge's discretion, the complaint may be amended to present current issues, but the judge may conclude that a new action based on a new record would better present any such issues. The declaratory

judgment shall be supplemented and amended to be consistent with this opinion and to resolve any undecided issues as to which there is an actual controversy.[11]

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[11] Plaintiffs' counsel could have greatly enhanced their presentation, the court's ability to deal with that presentation, and the defendants' manner of response by presenting each contention separately with supporting authority rather than grouping several points under one general topic. The issues in a case of this character are complicated by the interaction of Federal and State statutes and regulations. The facts bearing on these issues are often crucial to an understanding of them and to their resolution and should be discussed in the analysis of the issues. It is also instructive if an advocate explains why the alleged illegality of an agency regulation or any agency's course of conduct matters to the advocate's client.

Supreme Judicial Court for the
Commonwealth of Massachusetts
1412 Courthouse
Boston, Massachusetts 02108
(617) 557-1020

Edward D. Kalman, Esquire
Behar & Kalman
6 Beacon Street
Boston MA 02108

RE: No. SJC-06226

JEWISH MEMORIAL HOSPITAL & others
vs.
COMMONWEALTH & others

NOTICE OF DENIAL OF PETITION FOR REHEARING

The Petition for Rehearing filed in the above captioned case has been considered by the court and is denied.

Very truly yours,

Jean M. Kennett, Clerk

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Dated: September 23, 1993

To: Edward D. Kalman, Esquire
Rochelle H. Zapol, Esquire
Judith Fabricant, Esquire

RELEVANT STATUTES AND REGULATIONS

106 CMR 435.401

The challenged regulation codified at 106 CMR 435.401 provided as follows:

435.401: Introduction

(A) Participation 100 CMR 435.000 contains regulations governing participation in the Massachusetts Medical Assistance Program by chronic disease, rehabilitation, and Massachusetts Department of Public Health hospitals or units within other facilities performing chronic disease or rehabilitation services.

(B) Preadmission Screening. 106 CMR 435.000 describes the preadmission screening program for chronic disease and rehabilitation hospitals and applies to both in-state and out-of-state hospitals. The screening program described in this section is intended to ensure that medical and nursing services are provided in the most appropriate and cost-effective setting. The Department will pay for chronic disease ~~and~~ rehabilitation hospital services only when the Department or its agent authorizes these services based on a submission that establishes need prior to admission. (In order to expedite the process, approval may be given by telephone;

however, authorization of payment is contingent upon receipt of the completed Specialty Hospital Assessment Form.) Preadmission screening does not apply to hospital patients who were covered by other insurance (including Medicare) during part of a hospital stay and whose insurance coverage terminated prior to discharge.

(1) Hospitals with Delegated Status. Delegated hospitals shall document each recipient's need for hospitalization by completing the Department's Specialty Hospital Assessment Form and forwarding it to the Department's Long Term Care Connection (LTCC) within seven days of admission. Based on the hospital's determination, the LTCC staff will issue payment authorization forms to the recipient and to the appropriate Long Term Care Unit of the Department.

(2) Hospitals without Delegated Status.

(a) If a hospital routinely administers preadmission screenings and interviews, the hospital must complete the Specialty Hospital Assessment Form and submit it to the LTCC prior to admission.

(b) Other hospitals must notify the LTCC of impending admission. An in-person evaluation will be conducted

by an LTCC nurse to make an initial determination of the recipient's medical eligibility for admission in accordance with 106 CMR 435.000. Once a determination is made, the LTCC staff will issue payment authorization forms to the recipient and to the appropriate Long Term Care Unit.

(3) Noncoverage Determination.

In the event that the LTCC nurse's initial determination is that the recipient does not meet the level-of-care criteria of 106 CMR 435.409, the LTCC nurse shall contact the utilization-review coordinator of the hospital to determine the completeness of the medical record.

If the record is complete and no additional information is provided by the utilization-review coordinator, then the LTCC nurse shall refer the case for physician reconsideration upon the patient's request. The reconsideration will be conducted between the Department's nurse and the recipient's physician. If the Department's nurse and the recipient's physician disagree, an independent

physician in the same practice specialty as the attending physician, shall decide, utilizing the principles of medical peer review. A final determination of noncoverage will be made only by a physician.

106 CMR 435.409

The challenged regulation codified at 106 CMR 435.409 provided as follows:

> 435.409 Level-of-Care Criteria for Recipients in Chronic Disease and Massachusetts Department of Public Health Hospitals
>
> The criteria in 106 CMR 435.409 apply only to those recipients admitted to a hospital on or after the effective date of 106 CMR 435.409.

(A) Recipient Placement. The following level-of-care criteria will be used by the Department or its agent to determine the medical necessity and appropriateness of placement in chronic disease and Massachusetts Department of Public Health hospitals. Services in such hospitals are reimbursable only when available alternatives do not meet the recipient's needs, the services have been determined not to be reimbursable through Medicare or other insurance, and the recipient meets the level-of-care criteria listed in 106 CMR 435.409(A)(1). In applying these general criteria, the evaluator shall use as a guide the

Adult Appropriateness Evaluation Protocol (AEP) as used by the Peer Review Organization (PRO). The decision regarding the appropriateness of placement should not be based on the recipient's condition on the day of assessment, but must be based on the recipient's overall care plan and need for care as defined in 106 CMR 435.409(A), including the provisions listed in 435.409(A)(1) or (2).

(1) The recipient meets the following criteria:

(a) the recipient's medical condition warrants medically necessary services;

(b) the services are the type that, in light of the recipient's medical condition, can be provided safely and effectively, and cannot be provided at a lower level of care or less-costly setting (for example, a nursing facility or noninstitutional setting); and

(c) the recipient's medical condition and treatment require daily or more frequent physician supervision, or the recipient's medical condition and treatment require the constant availability of

medical services and equipment ordinarily available only in a hospital setting; or

(2) It can be shown that care in a chronic disease hospital is more cost effective, as clinical staff of the Department's medical case management program, than care in an alternative setting, and the recipient's complex medical condition prevents an alternative placement.

(B) Notice and Appeal. The notice and appeal provisions of the Department's administrative and billing regulations at 106 CMR 450.207(H) and (I) shall apply to preadmission screening decisions governed by 106 CMR 435.409.

106 CMR 435.410

The challenged regulation codified at 106 CMR 435.410 provided as follows:

435.410: Level-of-Care Criteria for Recipients Admitted to Chronic Disease Hospitals Prior to Effective Date of 106 CMR 435.409

(A) The criteria in 106 CMR 435.410 apply to those recipients admitted to a hospital prior to the effective date of 106 CMR 435.409.

(B) In order to be considered an appropriate chronic disease hospital placement, a recipient must require nursing services seven days a week for an average of 4.5 hours daily. On average, at least 1.5 hours of this nursing care must consist of skilled nursing services. Skilled nursing services include, but are not limited to, the following:

(1) nursing observation and care for a recipient's unstable or complex medical condition (for example, brittle diabetes or blood dyscrasia);

(2) administration of oral or injectable medications that require the judgment and direction of a registered nurse to monitor the dosage

and frequency and to observe the recipient for any adverse reactions to the medication. Drugs with life-threatening side effects, given as treatment for an acute condition, may require skilled nursing care. Administration of the same drug, given in a reduced dosage as a maintenance regimen, does not, in itself, indicate the need for skilled nursing care, nor does a 24-hour medication regimen;

(3) nasopharyngeal aspiration and tracheotomy care; however, long-term care of a tracheotomy tube does not, in itself, indicate the need for skilled nursing services;

(4) levin tube and gastrostomy feedings;

(5) administration of parenteral solutions on a regular and continuous basis;

(6) care of a colostomy either during an early postoperative period when related medical complications are present or when provided in combination with colostomy training. General continuous maintenance care of a colostomy can usually be performed by the patient himself or by a person without skilled training and, therefore, does not, in

itself, indicate the need for skilled nursing services;

(7) care of a suprapubic catheter or care of a urethral catheter when the insertion and maintenance of the urethral catheter is part of an active treatment for a disease of the urinary tract and irrigation is required for medical reasons (for example, when a recipient has cancer of the bladder or a resistant bladder infection).

(a) When care of a urethral catheter is the basis for recommending or approving the need for skilled nursing care, the urethral catheter must be prescribed by a physician and the need for the catheter must be documented in the recipient's medical record.

(b) The presence of a urethral catheter, particularly one placed for convenience, for the control of incontinence, or for routine irrigation, does not, in itself, indicate the need for skilled nursing care.

(c) For the purposes of 106 CMR 435.410(B)(7), a urinary tract infection caused by the use of a catheter does not

constitute a disease condition.

(8) administration of oxygen or other medical gases when they are needed on a regular and continuing basis because of the recipient's medical condition (for example, when the recipient has chronic obstructive pulmonary disease or pulmonary edema); and

(9) treatment of deep decubitus ulcers (deep area with or without necrotic tissue) or deep skin lesions when the physician has prescribed irrigation or the application of medication or sterile dressings. Infected skin lesions may require skilled nursing care to prevent the spread of the infection to other patients. When care of infected skin lesions is the basis for recommending or approving the need for skilled nursing care, the need must be documented in the recipient's medical record.

(C) In addition, the recipient must require, on average, treatment by a physician on a weekly basis. This physician intervention must be care that only a physician can provide, such as, but not limited to, the following:

(1) treatment given by the physician himself;
(2) changes in orders for treatments to be administered by the nursing staff;
(3) changes in orders for drugs to be administered by the nursing staff; and
(4) observations that can be made only by a physician.

The reason for the physician's visit, the observations made, and the proposed plan for continued treatment must be entered into the recipient's medical record. A diagnosis of terminal illness is not, in itself, sufficient reason for chronic disease hospitalization.

(D) Recipients who meet the requirements of 106 CMR 435.410(B) but do not meet the requirements of 106 CMR 435.410(C) will also be considered appropriate for chronic disease hospital placement if they are totally dependent in all activities of daily living and require at least three of the following treatments every day (or as otherwise indicated in 106 CMR 435.410(D)(1) through (10)), or if they have an assaultive or disruptive episode (here defined as one that requires controlling medication or restraint either by mechanical means or by one or more staff members) at least once weekly

and require at least three of the following treatments every day (or as otherwise indicated in 106 CMR 435.410(D)(1) through (10)):

(1) extensive dressing for deep decubiti, surgical wounds, or vascular ulcers;
(2) isolation;
(3) suctioning at least three times a week;
(4) occupational, physical, or speech/language therapy, or some combination of the three, at least five days a week;
(5) ostomy care, other than routine;
(6) oxygen;
(7) traction;
(8) wound or catheter irrigation;
(9) tube feeding; or
(10) skilled tracheostomy care

(E) The following are examples of appropriate chronic disease hospital placement:

(1) recipients who require suctioning/nasopharyngeal aspiration at least once per nursing shift or continuous use of a respirator (for example, intubation and mechanical ventilatory support);
(2) recipients with frequent life-threatening arrythmias that require monitoring and medical intervention;

(3) recipients whose severe electrolyte derangements are difficult to control;
(4) recipients with uncontrollable epileptic seizures at a frequency of more than three times weekly as documented in their medical records;
(5) recipients with multipal medical problems who are medicated with anticoagulants, chemotherapy for neoplastic diseases, or steroids that require a physician's evaluation or a drug regimen weekly;
(6) recipients receiving parenteral solutions on a frequent and continuous basis; and
(7) recipients with medical conditions that have required acute hospitalization in the past at least monthly and whose stay in a chronic disease hospital would preclude the necessity for the majority of these acute hospitalizations.

42 U.S.C. §1320c-1 provides that:

> The term "utilization and quality control peer review organization" means an entity which --
>
> (1)(A) is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1320c-2 of this title, with respect to which the entity shall perform services under this part, or (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;
>
> (2) is able, in the judgment of the Secretary, to perform review functions required under section 1320c-3 of this title in a manner

consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

(3) has at least one individual who is a representative of consumers on its governing body.

42 U.S.C. §1320c-3(a)(1)

provides that:

> Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions:
>
> > (1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and non-institutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under subchapter XVIII of this chapter (including where payment is made for such services to eligible organizations pursuant to contracts under section 1395mm of this title) for the purpose of determining whether --
> >
> > > (A) such services and items are or were reasonable and medically necessary and whether such services and items are not

allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

42 U.S.C. §1320c-7 provides as follows:

(a) State plan provision that functions of peer review organizations may be performed by contract with such organization

A State plan approved under subchapter XIX of this chapter may provide that the functions specified in section 1320c-3 of this title may be performed in an area by contract with a utilization and quality control peer review organization that has entered into a contract with the Secretary in accordance with the provisions of section 1395y(g) of this title.

(b) Federal share of expenditures

In the event a State enters into a contract in accordance with subsection (a) of this section, the Federal share of the expenditures made to the contracting organization for its costs in the performance of its functions under the State plan shall be 75 percent (as provided in section 1396b(a)(3)(C) of this title).

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42 U.S.C. §1395x(k) provides as follows:

(k) Utilization review

A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this subchapter and if it provides --

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B)

a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any

further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to subchapter XIX of this chapter are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this subchapter that the procedures established pursuant to subchapter XIX of this chapter be utilized instead of the procedures required by this section.

42 U.S.C. §1396a(a)(30)(A)

provides, in relevant part, that the state Medicaid agency must:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care;...

42 U.S.C. §1396b(g)(6)(A)

provides that:

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

42 U.S.C. §1396b(i)(4)

provides, in relevant part, that:

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1395x(k) of this title for purposes of subchapter XVIII of this chapter; and if such hospital has in effect such a utilization review plan for purposes of subchapter XVIII of this chapter, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this subchapter; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1395x(k) of this title;...

42 U.S.C. §1396n(b) provides as follows:

(b) Waivers to promote cost-effectiveness and efficiency

The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this subchapter, may waive such requirements of section 1396a of this title as may be necessary for a State--

(1) to implement a primary care case-management system or a specialty physician services arrangement which restricts the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain medical care services (other than in emergency circumstances), if such restriction does not substantially impair access to such services of adequate quality where medically necessary,

(2) to allow a locality to act as a central broker in assisting individuals (eligible for medical assistance under this subchapter) in selecting among competing health care plans, if such restriction does not substantially impair access

to services of adequate quality where medically necessary,

(3) to share (through provision of additional services) with recipients of medical assistance under the State plan cost savings resulting from use by the recipient of more cost-effective medical care, and

(4) to restrict the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain services (other than in emergency circumstances) to providers or practitioners who undertake to provide such services and who meet, accept, and comply with the reimbursement, quality, and utilization standards under the State plan, which standards are consistent with access, quality, and efficient and economic provision of covered care and services, if such restriction does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services.

No waiver under this subsection may restrict the choice of the

individual in receiving services under section 1396d(a)(4)(C) of this title.

42 C.F.R. §462.104(d) provides that:

> (d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of HCFA that it will act with complete independence and objectivity.

42 C.F.R. §482.30(c) provides that:

> The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.
>
> ...
>
> (c) Standard: Scope and frequency of review. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--
>
> (i) Admissions to the institution;
>
> (ii) The duration of stays; and
>
> (iii) Professional services furnished, including drugs and biologicals.
>
> (2) Review of admissions may be performed before, at, or after hospital admission.